

**REMARKS**

This Response, filed in reply to the Office Action dated August 9, 2007, is believed to be fully responsive to each point of objection and rejection raised therein. Accordingly, favorable reconsideration on the merits is respectfully requested.

Claim 4 is canceled. Claims 1-3 are amended. No new matter has been introduced by way of these claim amendments, and entry of this amendment is respectfully requested. Support for these amendments can be found throughout the originally filed specification, and at least in Examples 1-4. Upon entry of these amendments, Claims 1-3 will be pending in the application.

***Information Disclosure Statement***

Applicants thank the Examiner for returning a signed and initialed PTO Form SB/08 that accompanied the Information Disclosure Statement filed June 22, 2006.

Applicants note that the Examiner did not consider Japanese Patent No. 51-34151 because an English language translation was allegedly not provided. Applicants respectfully submit that Japanese Patent No. 51-34151 should be considered because this document was cited in an International Search Report (ISR), and an English translation of the ISR was submitted and acknowledged by the Examiner. Pursuant to M.P.E.P 609.04(a) III, "[w]here the information listed is not in the English language, but was cited in a search report or other action by a foreign patent office in a counterpart foreign application, the requirement for a concise explanation of relevance can be satisfied by submitting an English-language version of the search report or action which indicates the degree of relevance found by the foreign office."

Accordingly, Applicants respectfully request consideration of Japanese Patent No. 51-34151.

***Objections to the Specification***

On page 2 of the Office Action, the specification is objected to for use of the terms “Myocalm” and “Priscol.” The Office asserts that trademarks should either be written in upper case text, or should be accompanied by the registered trademark symbol, ®, and the generic terminology.

Applicants respectfully submit that the amendments to the specification attached herewith overcome the objection.

**Withdrawal of this objection is therefore respectfully requested.**

***Objections to the Claims***

On page 2 of the Office Action, Claim 3 is objected to on the ground that the claim language, as written, is awkward and either technically or grammatically incorrect. The Office asserts that, in view of the specification, the claim has been interpreted as being directed towards “a method for treating severe aphasia in a patient who has been diagnosed as having the severe aphasia as a consequence of chronic stage cerebrovascular accident.”

Solely to advance prosecution, and without acquiescing in the rejection, Applicants hereby amend Claims 1-3 to recite that the severe aphasia is “associated with cerebrovascular accident chronic stage.” Applicants respectfully submit that the amendments to the claims overcome the objection.

**Withdrawal of this objection is therefore respectfully requested.**

***Claims 3 and 4 are not Indefinite Under 35 U.S.C. § 112***

On page 3 of the Office Action, Claims 3 and 4 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The Office asserts that recitation of “a dose of from 9 to 40 g/day for a long term of 2 months or more” in Claim 3 is indefinite as it fails to adequately define the metes and bounds of the claim. Further, the Office asserts that Claim 3, as written, does not define an upper limit for treatment.

For clarification purposes only, Applicants hereby amend Claim 3 to recite “a dose of from 9g/day to 40g/day for at least 2 months.” Further, Applicants respectfully disagree with the Office’s assertion that an upper limit of treatment length need be defined. Applicants respectfully traverse the rejection, and point out that the claimed invention is clearly directed towards the treatment of a chronic condition, and thus, one of ordinary skill in the art would understand that an upper limit for treatment length is neither necessary, nor desirable in many cases. The management of chronic conditions often requires continual treatment, and ending such treatment often results in a relapse in symptoms. In this regard, although Applicant’s data demonstrates piracetam treatment is most efficacious in treating chronic aphasia if administered for at least two months, Applicants clearly indicate that piracetam may be used continuously in patients with chronic aphasia, as is indicated by use of the term “maintenance dose” within the Examples in the originally filed specification. Accordingly, Claim 3 is not indefinite under 35 U.S.C. § 112.

With regard to Claim 4, the Office asserts that the claim does not set forth any steps involved in the method or process, and consequently, it is unclear what method or process Applicant is claiming.

Without agreeing with the rejection, and solely to advance prosecution, Applicants hereby cancel Claim 4, rendering moot the rejection of this claim.

**Withdrawal of the rejection is therefore respectfully requested.**

***The Rejection of Claim 4 Under 35 U.S.C. § 101 is Moot***

On page 3 of the Office Action, Claim 4 is rejected under 35 U.S.C. § 101 for allegedly failing to set forth any steps involved in the claimed process.

Applicants respectfully submit that this rejection is moot in view of the cancellation of Claim 4.

***Claims 1, 2 and 4 are not Anticipated Under 35 U.S.C. § 102***

On page 4 of the Office Action, Claims 1, 2 and 4 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Huber (*Pharmacopsychiatry*, 1999, 32 (supp.), 38-43). The Office alleges that Huber discloses the administration of piracetam for the treatment of acute and chronic aphasia following stroke (which the Examiner interprets as being equivalent to “cerebrovascular accident”, as recited in the instant claims). Further, the Office alleges that Huber demonstrates that in patients suffering with post-acute and chronic aphasia (aphasia up to 3 years after stroke), improvement in speech occurred as a result of piracetam treatment.

Initially, Applicants respectfully submit that the rejection of Claim 4 is moot in view of the cancellation of this claim.

Further, Applicants respectfully submit that Claims 1 and 2 are not anticipated by Huber in view of the following remarks.

Applicants respectfully point out that Claims 1 and 2 have been amended to recite that the treatment is for patients having had aphasia for at least 3 years. Although the Office alleges that Huber demonstrates that an improvement in speech occurred as a result of piracetam treatment in patients suffering with chronic aphasia lasting up to 3 years after stroke, Applicants respectfully submit that Huber fails to disclose as such. Rather, a review of the original study (i.e. Huber *et al.* 1997, *Arch Phys Med Rehabil*, see Table 2) referenced by Table 2 of Huber discloses that the longest duration of aphasia that was treated with piracetam was 29 months. The only patients that had aphasia for 36 months (3 years) were those that were treated with a placebo, and thus not treated with piracetam. Furthermore, Huber indicates (Table 1 on page 247) that two patients were excluded on the ground that they had aphasia for too long (i.e., more than 36 months). Therefore, Huber fails to disclose the treatment of patients having had aphasia for at least three years with piracetam, as is mandated by instant Claims 1 and 2. Accordingly, Huber fails to disclose each and every element of the claims, as is required to maintain a rejection under 35 U.S.C. § 102(b).

Further, with specific regard to Claim 2, Applicants respectfully submit that in the study by Huber, piracetam was not used as the major treatment for patients having aphasia, but rather, Huber states that “piracetam, 4.8g daily for 6 weeks, [was used] as an adjuvant to intensive language therapy” (page 40, column 1, paragraph 2). Huber’s admission that piracetam was used as an “adjuvant” indicates that piracetam was used solely to enhance the effectiveness of the primary treatment, namely intensive language therapy. Thus, the use of piracetam as an adjuvant to intensive language therapy precludes the use of piracetam as the primary treatment for

aphasia. Indeed, the Huber reference fails to provide any evidence that administration of piracetam alone (i.e. in the absence of intensive language therapy) is efficacious in treating aphasia. Rather, Table 2 of Huber discloses that the only study using piracetam alone was not to treat aphasia, but to prevent the development of aphasia immediately following acute stroke. In contrast, Applicants respectfully submit that the claimed invention uses piracetam not as an adjuvant to another form of therapy, but as the major therapy. In this regard, to even further define Applicants' claimed invention, Claim 2 has been amended to recite "consisting essentially of" rather than "comprising." In addition, Claim 1 has been amended to recite "a composition" rather than "an agent", to even further clarify Applicants' intended invention. Accordingly, in view of the above remarks, Huber does not teach each and every element of the claim, and therefore does not anticipate Claims 1 and 2.

**Withdrawal of the rejection is therefore respectfully requested.**

***Claims 1-4 are not Obvious Under 35 U.S.C. § 103***

On page 5 of the Office Action, Claims 1-4 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Huber.

The Office alleges that in addition to the disclosures of Huber set forth in the rejection of Claims 1, 2, and 4 under 35 U.S.C. § 102(b), Huber also discloses that the dose of piracetam used in the post-acute and chronic aphasia study was 4.8 g/day for 6 weeks (*see* page 39, Table 2, 1<sup>st</sup> study). The Office admits that Huber fails to disclose a dose of piracetam within the range recited in instant Claim 3 (i.e., 9-40 g/day, for 2 months or more). Additionally, the Office admits that Huber does not teach that the chronic aphasia patients in the study had "no expectation of improvement" as is recited in Claim 3.

In an attempt to rectify the deficiencies of Huber, the Office asserts that although Huber does not disclose a dose of piracetam within the dose range disclosed in instant Claim 3, Huber discloses the use of piracetam at a dose of 12 g/day in an acute aphasia study. The Office alleges that one of ordinary skill in the art would use the doses and durations of treatment disclosed in the prior art only as a starting point for determining the most effective dose and length of treatment with piracetam, in view of an individual patient's clinical profile.

In addition, the Office asserts that although Huber does not disclose that the chronic aphasia patients in the study had "no expectation of improvement," the Merck Manual discloses that "any [ischemic stroke-related] deficit remaining after 6 mo[nths] is likely to be permanent." From this, the Office concludes that one skilled in the art could reasonably expect that individuals afflicted with stroke-induced aphasia, lasting for multiple years, would have no reasonable expectation of improving.

Initially, Applicants respectfully submit that the cancellation of Claim 4 renders moot the rejection of this claim. Further, Applicants respectfully submit that Claims 1-3 are not obvious over Huber at least in view of the above comments presented in response to the anticipation rejection. Specifically, Huber does not disclose treating aphasia with piracetam alone, but rather, discloses treating aphasia with intensive speech therapy using piracetam merely as an "adjuvant." In this regard, Applicants respectfully point out that Claims 2 and 3 have been amended to recite "consisting essentially of" rather than "comprising," precluding the use of piracetam as an adjuvant. Further, as mentioned above, the study relied upon by Huber fails to disclose the treatment of patients suffering with aphasia for at least 3 years after stroke with piracetam, as is mandated by the instant claims as amended. Accordingly, Claims 1-3 are not

rendered obvious because Huber fails to teach each and every element of the claims, as is required to maintain such a rejection.

In addition, Huber teaches one skilled in the art away from the claimed invention, as its experiments deliberately excluded patients having a duration of aphasia for more than 36 months. Table 1, page 247.

**Withdrawal of the rejection is therefore respectfully requested.**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.


The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

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